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November 15, 2005

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Art Unit: To Be Assigned**

**Attn: Mail Stop PCT**

Re: U.S. Utility Patent Application  
(U.S. National Phase of PCT/JP2004/005973; Int'l Filing Date: May 6, 2004)  
For: **Freeze-Dried Preparation Containing Methylcobalamin and Process  
For Producing Same**  
Inventors: KATO *et al.*  
Our Ref: 1089.0590000/SRL/NJL

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement Filing Under 37 C.F.R. § 1.97(b);
2. Form PTO/SB/08A listing eight (8) documents (FP1-FP8);
3. Form PTO/SB/08B listing fourteen (14) documents (NPL1-NPL14);
4. Copies of cited documents FP1-FP8 and NPL1-NPL14; and
5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
November 15, 2005  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Nancy J. Leith  
Agent for Applicants  
Registration No. 45,309

SRL/NJL/ja  
Enclosures

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

KATO *et al.*

Appl. No.: *To Be Assigned* (U.S. National  
Phase of PCT/JP2004/005973)

I.A. Filed: May 6, 2004

For: **Freeze-Dried Preparation  
Containing Methylcobalamin and  
Process For Producing Same**

Confirmation No.: *To Be Assigned*

Art Unit: *To Be Assigned*

Examiner: *To Be Assigned*

Atty. Docket: 1089.0590000/SRL/NJL

**Information Disclosure Statement  
Filing Under 37 C.F.R. § 1.97(b)**

*Mail Stop PCT*

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Forms PTO/SB/08A and PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of the documents are submitted herewith.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language documents **FP1-FP8** cited on Form PTO/SB/08A:

Document **FP1**, JP 45-38059 B1, is in the Japanese language. An unverified English abstract of FP1 is cited as document **NPL7**.

Document **FP2**, JP 55-113721 A, is in the Japanese language. An unverified English abstract of FP2 is cited as document **NPL8**. In addition, document FP2 was

cited in a search report by a foreign patent office in the international application. A copy of the search report indicating the relevance of said document is submitted herewith.

Document **FP3**, JP 59-152327 A, is in the Japanese language. An unverified English abstract of FP3 is cited as document **NPL9**. In addition, document FP3 was cited in a search report by a foreign patent office in the international application. A copy of the search report indicating the relevance of said document is submitted herewith.

Document **FP4**, JP 62-38 A, is in the Japanese language. An unverified English abstract of FP4 is cited as document **NPL10**.

Document **FP5**, JP 63-3137 A, is in the Japanese language. An unverified English abstract of FP5 is cited as document **NPL11**.

Document **FP6**, JP 1-132514 A, is in the Japanese language. An unverified English abstract of FP6 is cited as document **NPL12**.

Document **FP7**, JP 9-136837 A, is in the Japanese language. An unverified English translation of FP7 is cited as document **NPL13**. In addition, document FP7 was cited in a search report by a foreign patent office in the international application. A copy of the search report indicating the relevance of said document is submitted herewith.

Document **FP8**, JP 10-218775 A, is in the Japanese language. An unverified English translation of FP8 is cited as document **NPL14**. In addition, document FP8 was cited in a search report by a foreign patent office in the international application. A copy of the search report indicating the relevance of said document is submitted herewith.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

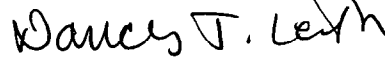
This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copies of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Nancy J. Leith  
Agent for Applicants  
Registration No. 45,309

Date: November 15, 2005

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> Number <sup>3</sup> Kind Code <sup>4</sup> (if known)				
/ZV/	FP1	JP 45-38059 B1	12/02/1970	Eisai Company Ltd.		
/ZV/	FP2	JP 55-113721 A	09/02/1980	Eisai Company Ltd.		
/ZV/	FP3	JP 59-152327 A	08/31/1984	Otsuka Pharmaceutical Company Ltd.		
/ZV/	FP4	JP 62-38 A	01/06/1987	Sankyo Company Ltd.		
/ZV/	FP5	JP 63-3137 A	01/08/1988	Matsushita Seiko Company Ltd.		
/ZV/	FP6	JP 1-132514 A	05/25/1989	Nippon Kayaku Company Ltd.		
/ZV/	FP7	JP 9-136837 A	05/27/1997	Merck Patent GmbH		
/ZV/	FP8	JP 10-218775 A	08/18/1998	Kaji Tatsuji		

Examiner Signature	/Zohreh Vakili/ (02/15/2008)	Date Considered	/Zohreh Vakili/ (02/15/2008)
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Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				Application Number	To Be Assigned (U.S. National Phase of PCT/JP2004/005973)
				I.A Filing Date	May 6, 2004
				First Named Inventor	Akira KATO
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	1	of	2	Attorney Docket Number	1089.0590000/SRL/NJL

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T <sup>2</sup>
/ZV/	NPL1	International Search Report for International Application No. PCT/JP2004/005973, Japanese Patent Office, mailed August 31, 2004	
/ZV/	NPL2	Izutsu, K.-i., <i>et al.</i> , "Effects of sodium tetraborate and boric acid on nonisothermal mannitol crystallization in frozen solutions and freeze-dried solids," <i>Int. J. Pharm.</i> 273:85-93, Elsevier B.V. (April 2004)	
/ZV/	NPL3	Izutsu, K.-i., <i>et al.</i> , "Decreased Protein-Stabilizing Effects of Cryoprotectants Due to Crystallization," <i>Pharm. Res.</i> 10:1232-1237, Plenum Publishing Corporation (1993)	
/ZV/	NPL4	Wu, S.-L., <i>et al.</i> , "The formation and mechanism of multimerization in a freeze-dried peptide," <i>Int. J. Pharm.</i> 200:1-16, Elsevier Science B.V. (2000)	
/ZV/	NPL5	Pikal, M.J., <i>et al.</i> , "The Effects of Formulation Variables on the Stability of Freeze-Dried Human Growth Hormone," <i>Pharm. Res.</i> 8:427-436, Plenum Publishing Corporation (1991)	
/ZV/	NPL6	Yoshinari, T., <i>et al.</i> , "Crystallization of amorphous mannitol is retarded using boric acid," <i>Int. J. Pharm.</i> 258:109-120, Elsevier Science B.V. (June 2003)	
	<del>NPL7</del>	<del>Dialog File 351, Accession No. 751840, Derwent WPI English abstract of JP 45-38050 B1, document EP1</del>	
	<del>NPL8</del>	<del>Patent Abstracts of Japan, unverified English abstract of JP 55-112721 A, document EP2</del>	
	<del>NPL9</del>	<del>Patent Abstracts of Japan, unverified English abstract of JP 59-152927 A, document EP3</del>	
	<del>NPL10</del>	<del>Patent Abstracts of Japan, unverified English abstract of JP 62-38 A, document EP4</del>	

Examiner Signature	/Zohreh Vakili/ (02/15/2008)	Date Considered	/Zohreh Vakili/ (02/15/2008)
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



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				Application Number	To Be Assigned (U.S. National Phase of PCT/JP2004/005973)
				I.A Filing Date	May 6, 2004
				First Named Inventor	Akira KATO
				Art Unit	To Be Assigned
Examiner Name	To Be Assigned				
Sheet	2	of	2	Attorney Docket Number	1089.0590000/SRL/NJL

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL11	<del>Patent Abstracts of Japan, unverified English abstract of JP 63-2137 A, document EP5</del>	
	NPL12	<del>Patent Abstracts of Japan, unverified English abstract of JP 1-132514 A, document EP6</del>	
	NPL13	<del>Patent Abstracts of Japan, unverified English translation of JP 9-136837 A, document EP7</del>	
	NPL14	<del>Patent Abstracts of Japan, unverified English translation of JP 10-218775 A, document EP8</del>	

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /ZV/ (06/21/2008)

Examiner Signature	/Zohreh Vakili/ (02/15/2008)	Date Considered	/Zohreh Vakili/ (02/15/2008)
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